Applicant: Rudi D. NEIRINCKX Application No. 09/584,978 Attorney Docket No. 2502491-991110 (formerly 44334)

## **REMARKS**

In the Advisory Action mailed April 1, 2004, the Examiner indicated that on filing of the executed Declaration, the Amendment would be entered and the finality of the Office Action would be removed.

Attached hereto is the executed Declaration of Neirinckx.

The claims amended above, which introduce no new matter, are clearly free of the cited art, for the reasons of record.

The above amendment to specification addresses what the Examiner wanted.

The same applies to the attached amended Abstract.

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## **CONCLUSION**

Applicant submits that the pending claims are in condition for allowance. Reexamination, reconsideration and early indication of allowance are requested respectfully. If any questions remain, the Examiner is urged to contact the undersigned at the local exchange noted below.

If any fees are found to be applicable, please charge any additional fees or make any credits to Deposit Account No. 07-1896.

Respectfully submitted, Dean H. Nakamura Registration No. 33,981

GRAY CARY WARE & FREIDENRICH LLP 1625 Massachusetts Avenue, N.W. Suite 300 Washington, D.C. 20036-2247 Telephone: (202) 238-7725 Facsimile: (202) 238-7701

Date: July 20, 2004

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## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Rudi D. NEIRINCKX

Group Art Unit: 1654

Examiner: Jeffrey E. RUSSEL

Application No. 09/584,978 Confirmation No. 5707

Filed: June 2, 2000

Atty. Docket No.

2502491-991110 (formerly 44334)

For: TREATMENT OF PSORIASIS THROUGH DOWN-REGULATION OF THE EGF-RECEPTOR WITH TOPICALLY-APPLIED EGF Customer No.

35928' 35928 PATENT TRADEMARK OFFICE

## DECLARATION UNDER 37 C.F.R. 1.132

Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 ATTN: Mail Stop AF

Sir:

1. I, Rudi Neirickx, am the inventor of the above-captioned application.

2. I hold a Ph.D. in Chemistry with 20 years experience in drug development.

3. I have been in communication with organizations in the human psoriasis

treatment field regarding my invention.

4. Because of the lack of a suitable human model, the companies that contacted me require human data. Following are representative quotes:

a. "To follow up with our previous correspondences and your recent

message to \_\_\_\_\_\_ office, I confirm that we have reviewed the preliminary Gray Cary/DC\14006032.1 2502491-9911 10

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information that you have provided. It appears that without having access to the clinical data generated with the 7 patients included in Skintek clinical trial it is difficult for us to confirm our interest. Please send us the details of the clinical data of the 7 patients so that our clinical experts review them and we will let you know if it is appropriate to have a meeting."

b. "If you have any more in vivo data or patient data you could provide this would greatly assist me in evaluating your technology."

5. That conclusion is supported by the FASEB J. Jackson et al. publication of record, published seven years after Nanney et al., which establishes the state of the art in 1999 that there was no animal model for psoriasis.

6. That conclusion is confirmed in the last full paragraph of Casaco et al.

7. Thus, there is no way to predict that a proposed treatment of psoriasis will be successful without an actual clinical trial.

8. I hereby declare that all statements made herein are of my own knowledge and are true, and that all statements made on information and belief are believed to be true, and further that the statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued therefrom.

9. Further Declarant sayeth not.

RD Meiruler

293, 2004

**Rudi Neirickx** 

Date